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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,125	11/26/2003	Paul A. Horgen	27,452-A USA	3235

23307 7590 04/03/2006

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EXAMINER
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WOOLWINE, SAMUEL C

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 04/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/723,125		HORGEN ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Samuel Woolwine		1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 March 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-4 and 11-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date: _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date: _____  | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group II, claims 5-10, and election of SEQ ID NOS:1-6, in the response filed 03/06/2006 is acknowledged. Claims 1-4 and 11-20 are withdrawn from further consideration.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5, 6 and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by GenBank GI:41901. As shown by the enclosed printout, this nucleotide sequence was known at least as early as 6 July 1989.

Regarding claim 5, since Applicant offers no specific definition of "amplicon" in the specification, the term imposes no structural limitation to distinguish the claimed invention from any nucleic acid sequence. In addition, the term "having" is not explicitly defined in the specification and is construed as open language. Therefore, the sequence of GenBank GI:41901 is an amplicon having a sequence which spans residues 2574-2895 of the *lacZ* gene of *E. coli*.

Regarding claim 6, the term "probe" is not explicitly defined in the specification, and therefore the term imposes no structural limitation to distinguish the claimed

invention from the sequence of GenBank GI:41901. The sequence itself can be used as a probe.

Regarding claim 8, since the sequence of GenBank GI:41901 comprises the sequence of SEQ ID NO:6, the invention of claim 8 is anticipated.

Regarding claim 9, the term "primer" is not explicitly defined in the specification, and therefore the term imposes no structural limitation to distinguish the claimed invention from the sequence of GenBank GI:41901. The sequence itself can be used as a primer. For example, it can be used to prime rolling circle amplification of *lacZ* cloned into a circular plasmid.

Regarding claim 10, since the sequence of GenBank GI:41901 comprises the sequences of SEQ ID NOS:4 and 5, the invention of claim 10 is anticipated.

Claims 5-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Senoo et al (2000).

Regarding claim 5, since Applicant offers no specific definition of "amplicon" in the specification, the term imposes no structural limitation to distinguish the claimed invention from any nucleic acid sequence. In addition, the term "having" is not explicitly defined in the specification and is construed as open language. Therefore, the recombinant adenoviral vector DNA shown in figure 1 and described in the first paragraph of the section entitled *Materials and Methods*, page 270, as well as the plasmid pUC-CAGGS-LacZ (see last sentence prior to the section entitled *Results*, page 271), both of which comprise the *E. coli lacZ* gene, are amplicons having a

sequence which spans residues 2574-2895 of the *lacZ* gene of *E. coli*. Additionally, the PCR product generated by Senoo (shown in figure 1 and described in the last paragraph of column 1, page 271) is an amplicon having a nucleotide sequence from the region spanning residues 2574-2895 of the *lacZ* gene of *E. coli*, since the entire *lacZ* gene itself is a region spanning residues 2574-2895.

Regarding claims 6 and 7, the TaqMan probe described in the last paragraph of column 1, page 271, meets the structural limitations of the claimed invention.

Regarding claim 8, since the recombinant adenoviral vector DNA shown in figure 1 and described in the first paragraph of the section entitled *Materials and Methods*, page 270, as well as the plasmid pUC-CAGGS-LacZ (see last sentence prior to the section entitled *Results*, page 271) each comprise the *lacZ* gene, these DNAs also comprise the sequence of SEQ ID NO:6. Since these DNAs can be used as probes, they anticipate the claimed invention since there is nothing in the claim language to structurally distinguish the claimed invention from these DNAs disclosed by Senoo.

Regarding claim 9, the term "primer" is not explicitly defined in the specification, and therefore the term imposes no structural limitation to distinguish the claimed invention from the sequences of the primers disclosed by Senoo in the last paragraph of column 1, page 271.

Regarding claim 10, the plasmid pUC-CAGGS-LacZ (see last sentence prior to the section entitled *Results*, page 271) comprises the *lacZ* gene. Therefore, this plasmid must necessarily comprise the sequence of SEQ ID NOS:4 and 5. This

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plasmid could be nicked and subjected to rolling circle amplification and thus serve as a primer.

### ***Conclusion***

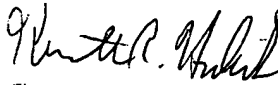
No claims are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Woolwine whose telephone number is (571) 272-1144. The examiner can normally be reached on Mon-Fri 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

scw

  
KENNETH R. HORLICK, PH.D  
PRIMARY EXAMINER  
3/30/06